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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| GENERAL ELECTRIC COMPANY GLOBAL RESEARCH PATENT DOCKET RM. BLDG. K1-4A59 NISKAYUNA, NY 12309 | | | LAVIN, CHRISTOPHER L | |
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| | | | 2621 | |

DATE MAILED: 11/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/683,111 | MUNDY ET AL. | |
| Examiner | Art Unit | | |
| Christopher L Lavin | 2621 | | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 20 November 2001.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1 - 58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1 - 33, 35 - 40, 42 - 58 is/are rejected.
- 7) Claim(s) 34 and 41 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 10 - 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Claim 10 recites the limitation "competing step" in the phrase "presenting the results of the competing step for use in identifying suspicious regions in the medical images". There is insufficient antecedent basis for this limitation in the claim.
4. Claims 11 – 19 are rejected as they depend from claim 10.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1 – 4, 8 – 11, 14, 16 – 23, 45 – 49, 51, and 55 – 58 rejected under 35 U.S.C. 102(b) as being anticipated by Brown (Matthew S. Brown et al., "Method For Segmenting Chest CT Image Data Using An Anatomical Model: Preliminary Results", IEEE Transactions on Medical Imaging, IEEE INC, New York, U.S., Vol. 16. No. 6. December 1997, pp. 828-839)

7. In regards to claim 1, Brown discloses a method for processing medical images for the detection of disease. On page 830, in the second column Brown discloses classifying regions of interest based on a hierarchy of anatomical models. As seen in Figure 2 Brown discloses anatomical models. In the first full paragraph in the second column Brown discloses that nodules are isolated, nodules which would be part of a hierarchy of the lung. A nodules is the leading indicator of cancer, and therefore indicative of a given disease. On page 831, Brown discloses in the first paragraph under category C. Image Processing “to segment a particular anatomical structure, its modeled range of X-ray attenuation in Hounsfield units is translated to upper and lower gray-level thresholds”. This is a signal model, based on signal information of an image acquisition device (X-Ray) used to acquire medical images.

8. In regards to claim 2, Brown discloses the step of presenting regions of interest in figure 17, which is further discussed on page 835. In the first paragraph under category B. Tumor Segmentation Brown discloses “A lung mass contacting the chest wall pleural was also successfully segmented (Fig. 17). The chest wall, spine, anterior junction line, and mediastinum were approximately segmented to guide the isolation of the lesion.” This is effectively displaying the regions of interest.

9. In regards to claim 3, Brown discloses on page 830 in the second paragraph under the category B. Anatomical Model that “each model parameter, whether it relates to size, shape, or position of an organ” and thus the anatomical model comprises of geometric information. In the third paragraph of the same category, Brown discloses

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that "the functions were determined empirically, in collaboration with radiologists and pulmonologists". Radiologists and pulmonologists are experts.

10. In regards to claim 4, on page 831 Brown discloses in the first paragraph under category C. Image Processing "to segment a particular anatomical structure, its modeled range of X-ray attenuation in Hounsfield units is translated to upper and lower gray-level thresholds". Thus an impulse response of the image acquisition (x-ray) device is used, X-ray brightness is used to threshold the image.

11. In regards to claim 6, Brown discloses on page 829 in the category C. Our Approach to Segmentation CT Image Data that Brown has "developed a knowledge-based fully automatic method for segmenting volumetric chest CT datasets".

12. In regards to claim 8, Brown discloses on page 829 that chest CTs are used as images for disease location. Inherently in such a statement is the need for a computer tomography scanner. On page 831 under the category C. Image Processing in the first paragraph Brown discloses that an X-ray device is used to obtain the chest image.

13. In regards to claim 9, Brown discloses on page 830 in the second column, first full paragraph that anatomical models are used to represent nodules, which are the diseased lung tissue.

14. In regards to claim 10, Brown discloses a method for processing medical images for the detection of disease. On page 830, in the second column Brown discloses classifying regions of interest based on a hierarchy of anatomical models. As seen in Figure 2 Brown discloses anatomical models. In the first full paragraph in the second column Brown discloses that nodules are isolated, nodules which would be part of a

hierarchy of the lung. A nodule is the leading indicator of lung cancer, and therefore indicative of a given disease. In category B. Anatomical Models Brown discloses that mathematical models (fuzzy logic) and tissue characteristics (size, shape, or position) are grouped together to represent the hierarchy of anatomical models. On page 831, Brown discloses in the first paragraph under category C. Image Processing "to segment a particular anatomical structure, its modeled range of X-ray attenuation in Hounsfield units is translated to upper and lower gray-level thresholds". This is a signal model, based on signal information of an image acquisition device (X-Ray) used to acquire medical images. Finally on page 833 in the first full paragraph in the second column Brown discloses a step of picking between competing scheduling and decision steps. "If mutual dependencies exist, then more than one frame may have equal precedence. In such a case, the inference engine and control systems must be able to reason with multiple frames simultaneously and find the best combination of candidates. This capability can be built into the knowledge based framework."

15. In regards to claim 11, on page 831 Brown discloses in the first paragraph under category C. Image Processing "to segment a particular anatomical structure, its modeled range of X-ray attenuation in Hounsfield units is translated to upper and lower gray-level thresholds". Thus an impulse response of the image acquisition (x-ray) device is used, X-ray brightness is used to threshold the image.

16. In regards to claim 14, Brown discloses the step of presenting regions of interest in figure 17, which is further discussed on page 835. In the first paragraph under category B. Tumor Segmentation Brown discloses "A lung mass contacting the chest

wall pleural was also successfully segmented (Fig. 17). The chest wall, spine, anterior junction line, and mediastinum were approximately segmented to guide the isolation of the lesion.” This is effectively displaying the regions of interest.

17. In regards to claim 16, Brown discloses on page 830 in the second paragraph under the category B. Anatomical Model that “each model parameter, whether it relates to size, shape, or position of an organ” and thus the anatomical model comprises of geometric information. In the third paragraph of the same category, Brown discloses that “the functions were determined empirically, in collaboration with radiologists and pulmonologists”. Radiologists and pulmonologists are experts.

18. In regards to claim 17, Brown discloses on page 830 in the first paragraph starting in the second paragraph and further in figure 2 anatomical models for lung nodules, vascular structure and lung parenchyma (Right and Left Parenchyma).

19. In regards to claim 18, Brown discloses on page 829 that chest CTs are used as images for disease location. Inherently in such a statement is the need for a computer tomography scanner. On page 831 under the category C. Image Processing in the first paragraph Brown discloses that an X-ray device is used to obtain the chest image.

20. In regards to claim 19, Brown discloses on page 830 in the third paragraph in category B. Anatomical Model that images of the lung are taken and diagnosed.

21. In regards to claim 20, on page 829 in the final paragraph of the category C. Our Approach to Segmentation of CT Image Data Brown discloses “we have initially applied this method to segment the chest wall, mediastinum, central tracheobronchial tree, and respective lungs in chest CT image data.” This is the step of segmenting the acquired

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image data to define the lung region. On page 831, Brown discloses in the first paragraph under category C. Image Processing "to segment a particular anatomical structure, its modeled range of X-ray attenuation in Hounsfield units is translated to upper and lower gray-level thresholds". This is the step of computing low level features in the images using the known characteristics of the imaging device (x-ray) and the imaging process. On page 830, in the second column Brown discloses classifying regions of interest based on a hierarchy of anatomical models. As seen in Figure 2 Brown discloses anatomical models. Thus a hierarchy of anatomical models is computed and regions are grouped into anatomical structures. In the first full paragraph in the second column Brown discloses that nodules are isolated, nodules which would be part of a hierarchy of the lung. A nodule is the leading indicator of lung cancer, and therefore indicative of lung disease.

22. In regards to claim 21, as disclosed above in the rejection of claim 20 suspicious areas (nodules) are identified. As shown in figure 17b Brown discloses presenting these areas.

23. In regards to claim 22, Brown discloses the step of presenting regions of interest in figure 17, which is further discussed on page 835. In the first paragraph under category B. Tumor Segmentation Brown discloses, "A lung mass contacting the chest wall pleural was also successfully segmented (Fig. 17). The chest wall, spine, anterior junction line, and mediastinum were approximately segmented to guide the isolation of the lesion." This is effectively displaying the suspicious areas. By displaying the segmented image and the original image (again for example Fig. 17) the method is

displaying the decision process. The segmentations made are the decisions which lead to the identification of the suspicious area.

24. In regards to claim 23, Brown discloses on page 829 that chest CTs are used as images for disease location. Inherently in such a statement is the need for a computer tomography scanner. On page 831 under the category C. Image Processing in the first paragraph Brown discloses that an X-ray device is used to obtain the chest image.

25. In regards to claim 45, Brown in the first paragraph in category A. Overall Architecture on page 820 discloses a system for processing medical images acquired by an image acquisition device. The operations described by Brown can only be performed by a computer and therefore require a processor. It is well known in the art that x-ray and other medical imaging devices can be attached to a computer (which is what Brown's system must be based around). On page 830, in the second column Brown discloses classifying regions of interest based on a hierarchy of anatomical models. As seen in Figure 2 Brown discloses anatomical models. In the first full paragraph in the second column Brown discloses that nodules are isolated, nodules which would be part of a hierarchy of the lung. A nodule is the leading indicator of lung cancer, and therefore indicative of a given disease. Brown's system therefore can be used for the diagnosis and detection of disease. On page 831, Brown discloses in the first paragraph under category C. Image Processing "to segment a particular anatomical structure, its modeled range of X-ray attenuation in Hounsfield units is translated to upper and lower gray-level thresholds". This is a signal model, based on signal information of an image acquisition device (X-Ray) used to acquire medical images.

Brown also disclose in figure 17 information relating to the suspicious region. Inherently Brown must have some sort of interface to provide this information.

26. In regards to claim 46, Brown discloses the step of presenting regions of interest in figure 17, which is further discussed on page 835. In the first paragraph under category B. Tumor Segmentation Brown discloses "A lung mass contacting the chest wall pleural was also successfully segmented (Fig. 17). The chest wall, spine, anterior junction line, and mediastinum were approximately segmented to guide the isolation of the lesion." This is effectively displaying the regions of interest.

27. In regards to claim 47, Brown discloses on page 829 that chest CTs are used as images for disease location. Inherently in such a statement is the need for a computer tomography scanner. On page 831 under the category C. Image Processing in the first paragraph Brown discloses that an X-ray device is used to obtain the chest image.

28. In regards to claim 48, Brown discloses on page 830 in the second column and in figure 2 that lung nodules, blood vessels, and lung parenchyma are part of the hierarchy of anatomical models. Lung nodules are indicative of lung cancer.

29. In regards to claim 49, as shown above Brown specifies a hierarchy with increasing complexity. Starting at just the lung outline, going to the right and left lungs, defining the paraenchnyma, lung nodules and blood vessels. Each step requires greater complexity to differentiate models from one another. Therefore the hierarchy must comprise models of increasing complexity for use in identifying regions of a given disease in this case lung cancer.

30. In regard to claim 51, Brown discloses in the third paragraph in the category B. Anatomical Model on page 830 that right and left lungs are segmented. For this to be the case the medical image must be of a lung.

31. In regards to claim 55, Brown discloses on page 832 in the first paragraph under category D. Inference Engine that fuzzy logic is used to determine which anatomical model to assign to a region of interest. In order to use fuzzy logic a neural network is needed to analyze the data sets. Therefore Brown inherently specifies a neural network. One of the core concepts behind neural networks is the ability to adapt and change based on past results. So the processor disclosed by Brown must have the ability to tune at least one computer analysis algorithm based on information from model hierarchy computations stored in previous exams.

32. In regards to claim 56, Brown discloses on page 832 in the first paragraph under category D. Inference Engine that fuzzy logic is used to determine which anatomical model to assign to a region of interest. In order to use fuzzy logic a neural network is needed to analyze the data sets. Therefore Brown inherently specifies a neural network. The fuzzy sets are based on statistical measurements from previous exams. The system, must inherently, generate statistical measurements for these fuzzy sets.

33. In regards to claim 57, Brown discloses a system where the results are based on statistical measurements. As shown in previous claims the system disclosed by Brown has the ability to display or in this case report these results to a local or remote location.

34. In regards to claim 58, the results generated by Brown include three-dimensional images, for example figures 13 and 14. If a remote system accessing this information,

for example a handheld device used by a doctor, was unable to handle particular type of data the processor disclosed by Brown inherently must have some way to determine the capability of the display.

Claim Rejections - 35 USC § 103

35. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

36. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

37. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

38. Claims 5, 7, 12, 13, 24 – 33, 35 – 37, 39, 40, and 42 – 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown in view of Tewari (6,004,267).

39. In regards to claim 5, Brown discloses on page 832 in the first paragraph under category D. Inference Engine that fuzzy logic is used to determine which anatomical model to assign to a region of interest. In order to use fuzzy logic a neural network is needed to analyze the data sets. So Brown inherently specifies a neural network; however, Brown does not disclose how that neural network will be implemented.

40. Tewari teaches in the paragraph starting at column 11, line 15 that “probabilistic neural networks are based on Bayes decision theorem and nonparametric statistics to calculate the probability density function.” Tewari teaches that Bayes Factors can be used to classify items.

41. Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to use a neural network with Bayes Factors to classify tissue types. When dealing with classifying items that are not always entirely similar neural networks are ideal, using Bayes Factors for such a neural network is the best choice since such networks are based on training sets (which Brown discloses are used).

42. In regards to claim 7, Brown discloses the step of presenting regions of interest in figure 17, which is further discussed on page 835. In the first paragraph under category B. Tumor Segmentation Brown discloses “A lung mass contacting the chest wall pleural was also successfully segmented (Fig. 17). The chest wall, spine, anterior junction line, and mediastinum were approximately segmented to guide the isolation of the lesion.” This is effectively displaying the regions of interest.

43. In regards to claims 12 and 13, Brown discloses on page 832 in the first paragraph under category D. Inference Engine that fuzzy logic is used to determine which anatomical model to assign to a region of interest. In order to use fuzzy logic a neural network is needed to analyze the data sets. So Brown inherently specifies a neural network; however, Brown does not disclose how that neural network will be implemented.

44. Tewari teaches in the paragraph starting at column 11, line 15 that "probabilistic neural networks are based on Bayes decision theorem and nonparametric statistics to calculate the probability density function." Tewari teaches that Bayes Factors can be used to classify items.

45. Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to use a neural network with Bayes Factors to classify tissue types. When dealing with classifying items that are not always entirely similar neural networks are ideal, using Bayes Factors for such a neural network is the best choice since such networks are based on training sets (which Brown discloses are used).

46. In regards to claim 24, Brown discloses on page 832 in the first paragraph under category D. Inference Engine that fuzzy logic is used to determine which anatomical model to assign to a region of interest. In order to use fuzzy logic a neural network is needed to analyze the data sets. So Brown inherently specifies a neural network; however, Brown does not disclose how that neural network will be implemented.

47. Tewari teaches in the paragraph starting at column 11, line 15 that "probabilistic neural networks are based on Bayes decision theorem and nonparametric statistics to

calculate the probability density function." Tewari teaches that Bayes Factors can be used to classify items.

48. Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to use a neural network with Bayes Factors to classify tissue types. When dealing with classifying items that are not always entirely similar neural networks are ideal, using Bayes Factors for such a neural network is the best choice since such networks are based on training sets (which Brown discloses are used).

49. In regards to claim 25, Brown discloses a method for processing medical images for the detection of disease. On page 830, in the second column Brown discloses classifying regions of interest based on a hierarchy of anatomical models. As seen in Figure 2 Brown discloses anatomical models. In the first full paragraph in the second column Brown discloses that nodules are isolated, nodules which would be part of a hierarchy of the lung. A nodule is the leading indicator of lung cancer, and therefore indicative of a given disease. Brown discloses on page 832 in the first paragraph under category D. Inference Engine that fuzzy logic is used to determine which anatomical model to assign to a region of interest. In order to use fuzzy logic a neural network is needed to analyze the data sets. So Brown inherently specifies a neural network; however, Brown does not disclose how that neural network will be implemented.

50. Tewari teaches in the paragraph starting at column 11, line 15 that "probabilistic neural networks are based on Bayes decision theorem and nonparametric statistics to calculate the probability density function." Tewari teaches that Bayes Factors can be used to classify items.

51. Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to use a neural network with Bayes Factors to classify tissue types. When dealing with classifying items that are not always entirely similar neural networks are ideal, using Bayes Factors for such a neural network is the best choice since such networks are based on training sets (which Brown discloses are used).

52. In regards to claim 26, Brown discloses on page 830 in the second paragraph under the category B. Anatomical Model that "each model parameter, whether it relates to size, shape, or position of an organ". Thus the anatomical model comprises of geometric information.

53. In regards to claim 27, on page 831, Brown discloses in the first paragraph under category C. Image Processing "to segment a particular anatomical structure, its modeled range of X-ray attenuation in Hounsfield units is translated to upper and lower gray-level thresholds". This is a signal model, based on signal information of an image acquisition device (X-Ray) used to acquire medical images. There are a plurality of signal models that could be used including density, brightness, resolution, and contrast.

54. In regards to claim 28, as shown above Brown discloses signal models and anatomical models the signal models are used to threshold images, this is a low level step in the hierarchy. The thresholded images are then further segmented by the anatomical models, using anatomical models is a high level in the hierarchy. Finally, Brown discloses on page 830 under the category B in the third paragraph "the functions were determined empirically, in collaboration with radiologists and pulmonologists". Radiologists and pulmonologists are experts.

55. In regards to claim 29, as shown above Brown discloses a multilevel hierarchy for example first the lung outline is found, then the right and left lungs are identified and then individual nodules are located. All of these modules are based on geometric, shape, and intensity information (see figure 2 for an example, each model has an intensity specified) and therefore are intermediate levels defining geometric models, shape models and intensity models.

56. In regards to claim 30, Brown discloses on page 830 in the second column, first full paragraph that anatomical models are used to represent nodules, which are the diseased lung tissue.

57. In regards to claim 31, as shown in the rejection of claim 30 Brown discloses that anatomical models correspond to lung nodules which are indicative of lung disease. On page 830 in the second column second paragraph Brown discloses "Nodules may be anatomically contiguous with blood vessels". Inherent in such a statement is the requirement for some sort of anatomical model for blood vessels. Finally the remaining tissue (lung matrix tissue) is represented in the lung parenchyma anatomical models (see figure 2).

58. In regards to claim 32, as shown above Brown discloses a multilevel hierarchy for example first the lung outline is found, then the right and left lungs are identified and then individual nodules are located. All of these modules are based on shape and intensity information (see figure 2 for an example, each model has an intensity specified) and therefore are intermediate levels defining shape models and intensity models. Some of these models must be characteristic of lung nodules.

59. In regards to claim 33, as shown above in the rejection of claim 32 intermediate levels defining shape models and intensity models exist for lung nodules, as lung vessels also must be identified as shown in the final paragraph on page 830. "Compactness is an important shape feature in distinguishing nodules from vessels." Inherent in such a statement is the requirement for some sort of anatomical model for blood vessels and therefore a plurality of intermediate levels defining shape models and intensity models are characteristic of lung vascular structure.

60. In regards to claim 35, Brown in the first paragraph in category A. Overall Architecture on page 820 discloses a system for processing medical images acquired by an image acquisition device. The operations described by Brown can only be performed by a computer and therefore require a processor. It is well known in the art that x-ray and other medical imaging devices can be attached to a computer (which is what Brown's system must be based around). On page 830, in the second column Brown discloses classifying regions of interest based on a hierarchy of anatomical models. As seen in Figure 2 Brown discloses anatomical models. In the first full paragraph in the second column Brown discloses that nodules are isolated, nodules which would be part of a hierarchy of the lung. A nodules is the leading indicator of cancer, and therefore indicative of a given disease. On page 831, Brown discloses in the first paragraph under category C. Image Processing "to segment a particular anatomical structure, its modeled range of X-ray attenuation in Hounsfield units is translated to upper and lower gray-level thresholds". This is a signal model, based on signal information of an image acquisition device (X-Ray) used to acquire medical

images. Brown also disclose in figure 17 information relating to the suspicious region. Inherently Brown must have some sort of interface to provide this information. Brown discloses on page 832 in the first paragraph under category D. Inference Engine that fuzzy logic is used to determine which anatomical model to assign to a region of interest. In order to use fuzzy logic a neural network is needed to analyze the data sets. So Brown inherently specifies a neural network; however, Brown does not disclose how that neural network will be implemented.

61. Tewari teaches in the paragraph starting at column 11, line 15 that "probabilistic neural networks are based on Bayes decision theorem and nonparametric statistics to calculate the probability density function." Tewari teaches that Bayes Factors can be used to classify items.

62. Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to use a neural network with Bayes Factors to classify tissue types. When dealing with classifying items that are not always entirely similar neural networks are ideal, using Bayes Factors for such a neural network is the best choice since such networks are based on training sets (which Brown discloses are used).

63. In regards to claim 36, Brown discloses on page 830 in the second column, first full paragraph that anatomical models are used to represent nodules, which are the diseased lung tissue.

64. In regards to claim 37, as shown above Brown specifies a hierarchy with increasing complexity. Starting at just the lung outline, going to the right and left lungs, defining the paraenchyma, lung nodules and blood vessels. Each step requires greater

complexity to differentiate models from one another. Therefore the hierarchy must comprise models of increasing complexity for use in identifying suspicious regions.

65. In regards to claim 39, on page 831 Brown discloses in the first paragraph under category C. Image Processing "to segment a particular anatomical structure, its modeled range of X-ray attenuation in Hounsfield units is translated to upper and lower gray-level thresholds". Thus an impulse response of the image acquisition (x-ray) device is used, X-ray brightness is used to threshold the image.

66. In regards to claim 40, Brown discloses on page 829 that chest CTs are used as images for disease location. Inherently in such a statement is the need for a computer tomography scanner. On page 831 under the category C. Image Processing in the first paragraph Brown discloses that an X-ray device is used to obtain the chest image.

67. In regards to claim 42, as discussed above the system disclosed by Brown segments a chest CT. It segments the Lung region into lung matrix tissue, lung nodules and blood vessels.

68. In regards to claim 43, as disclosed above a plurality of anatomical and signal models are grouped together into a hierarchy of models. Brown discloses on page 832 in the second paragraph of category D. Interface Engine that "an overall confidence score for the candidate is derived by taking the minimum of all constraint confidence scores, i.e., a fuzzy logic approach. The candidate with the highest confidence is selected for matching to the model." So the hierarchy of models is used in the competitive framework, which is based on a neural network (Fuzzy Logic).

69. In regards to claim 44, Brown discloses in the third paragraph in the category B. Anatomical Model on page 830 that right and left lungs are segmented. For this to be the case the medical image must be of a lung.

70. Claims 15 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown in view of Gray (6,004,267).

71. In regards to claim 15, Brown discloses a method for processing a medical image for use in the detection and diagnosis of disease. Brown however does not specify a user interface for inputting queries regarding the anatomical context of each suspicious region.

72. Gray teaches in the paragraph starting at column 2, line 53 that a user interface can be set up to allow a user to specify a particular area of interest. "The illustrative method therefore allows a user to input, for a given patient, data concerning the location of the primary and any cluster of lymph nodes which are known to be infected."

73. Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to allow a user to input areas of interest into the method disclosed by Brown. By letting a user roughly point out a suspicious area the method disclosed by Brown can more accurately diagnose the image.

74. In regards to claim 50, Brown discloses a system for processing a medical image for use in the detection and diagnosis of disease. Brown however does not specify a user interface for inputting queries regarding the anatomical context of each suspicious region or a decision process for identifying each of the suspicious regions.

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75. Gray teaches in the paragraph starting at column 2, line 53 that a user interface can be set up to allow a user to specify a particular area of interest. "The illustrative method therefore allows a user to input, for a given patient, data concerning the location of the primary and any cluster of lymph nodes which are known to be infected." This data can be anatomical context or a decision process.

76. Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to allow a user to input areas of interest or decision processes into the system disclosed by Brown. By letting a user roughly point out a suspicious area the system disclosed by Brown can more accurately diagnose the image. By letting the user specify a particular decision, such as the classification of an item that the system is having difficulty with, a more accurate overall diagnoses can be reached.

77. Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brown in view of Tewari as applied to claim 35 above, and further in view of Gray.

78. In regards to claim 38, Brown discloses a system for processing a medical image for use in the detection and diagnosis of disease. Brown however does not specify a user interface for inputting queries regarding the anatomical context of each suspicious region or a decision process for identifying each of the suspicious regions.

79. Gray teaches in the paragraph starting at column 2, line 53 that a user interface can be set up to allow a user to specify a particular area of interest. "The illustrative method therefore allows a user to input, for a given patient, data concerning the location of the primary and any cluster of lymph nodes which are known to be infected." This data can be anatomical context or a decision process.

Art Unit: 2621

80. Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to allow a user to input areas of interest or decision processes into the system disclosed by Brown. By letting a user roughly point out a suspicious area the system disclosed by Brown can more accurately diagnose the image. By letting the user specify a particular decision, such as the classification of an item that the system is having difficulty with, a more accurate overall diagnosis can be reached.

81. Claims 52 – 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown in view of Teshima (6,272,470).

82. In regards to claim 52, Brown discloses the system of claim 45 inherent in such a system is some form of storage for storing both the medical images and the results. Brown however does not disclose a means for accessing that information through a network.

83. Teshima teaches in the paragraph starting at column 1, line 53 a medical-image management system for storing, retrieving, transmitting and displaying medical images. Teshima teaches this information can be retrieved over a network, "integrated services digital network is used to transmit information". In the paragraph starting at column 2, line 15 Teshima discloses that a SQL database is used to store all of the information used for the system. One of the primary uses of SQL is an efficient search. Therefore Teshima discloses a system for storing the data created by Brown, which can be searched to retrieve that data over a network.

84. Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to allow remote searching and retrieval of the data stored in the

system disclosed by Brown. By allowing remote retrieval of data, the results from Brown, which most likely consist of many high resolution images will not need to be taken from the native media (digital images) and placed on paper that would limit the detail level of the images.

85. In regards to claim 53, Teshima discloses in the paragraph starting at column 1, line 53 that "ISDN is used to transmit information of medical images and to ask a specialist to send back the results of diagnosis." The system disclosed by Brown in view of Teshima would be the specialist in this situation. After processing the request the system would have to send detailed information back, over a network, to the requesting party, who would have to be located at a workstation in order to receive the information. Detailed information could include high-resolution images, preliminary diagnosis, and statistics. Allowing remote requests for diagnoses would limit the need for more than one system disclosed by Brown in view of Teshima in a medical facility saving a great deal of money.

86. In regards to claim 54, as disclosed in claim 53 the system would have to send detailed information back to the requesting party. For such a system to be useful to medical professional it would have to be designed to send back particular information. For example, it would be useless if the system did not send back high-resolution images with suspicious areas marked. So specific requirements are inherently required in the system disclosed by Brown in view of Teshima.

Allowable Subject Matter

87. Claims 34 and 41 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

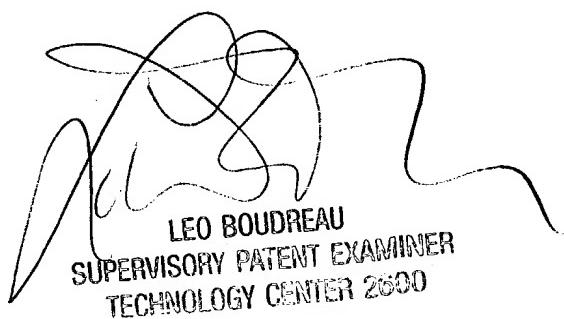
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher L Lavin whose telephone number is 703-306-4220. The examiner can normally be reached on M - F (8:30 - 5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Leo Boudreau can be reached on (703) 305-4706. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CLL



LEO BOUDREAU
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 2600